

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Namenda Direct Purchaser Antitrust
Litigation

THIS DOCUMENT RELATES TO:
All Direct Purchaser Actions

Case No. 1:15-cv-07488-CM (RL)

FILED UNDER SEAL

**MEMORANDUM OF LAW IN SUPPORT OF FOREST'S MOTION TO EXCLUDE
CERTAIN OPINIONS AND PROPOSED TESTIMONY OF PROF. EINER ELHAUGE**

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I. INTRODUCTION

Proposed Plaintiff expert Einer Elhauge, a law professor, intends to testify that, according to a mathematical model he constructed, Forest and Mylan would have settled the Namenda IR patent litigation for “no payment” and a generic entry date [REDACTED].

As discussed in more detail below, Prof. Elhauge’s model ignores that only “large” and “unjustified” reverse payments may be subject to antitrust scrutiny. *Sergeants Benevolent Ass’n Health & Welfare Fund v. Actavis, plc*, No. 15-cv-7488, 2016 U.S. Dist. LEXIS 128349, at *41-42 (S.D.N.Y. Sept. 13, 2016) (“*Namenda I*”). Instead, it presumes that *any* payment, regardless of its size or the reasons for making it, *causes* anticompetitive delay. Moreover, the model depends on unrealistic assumptions and leads to results that are contrary to economic sense and the facts of the case. But even if the model comported with applicable law and the actual facts, Prof. Elhauge intends to use the model to usurp the role of the jury and opine that Forest and Mylan *actually would have settled* the patent litigation for “no payment” and generic entry as of [REDACTED]. Binding precedent from the Second Circuit prohibits this type of expert testimony, however, and indisputable evidence shows that the settling entities *would not* have agreed to a generic entry date more than three months before the Namenda IR patent expired.

Therefore, the Court should strike Prof. Elhauge’s opinions on this topic and preclude him from testifying about alternative generic entry dates that he believes Forest and Mylan would or could have agreed to in a hypothetical patent litigation settlement.

II. BACKGROUND

Prof. Elhauge purports to use “economic analysis” to analyze [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] and (4) whether there were “procompetitive justifications for the reverse payment.” Decl. of Michael E. Hamburger, Ex. 1 (Revised Expert Report of Prof. Einer Elhauge, dated Sept. 20, 2017) (“Elhauge Rep.”) ¶¶ 1-2. Prof. Elhauge was specifically asked to model a but-for world “with no payment.” Hamburger Decl., Ex. 14 (Elhauge Dep. Tr. I) at 80:11-17.

Prof. Elhauge developed the methodology he uses here before the Supreme Court’s decision in *Actavis*, and debuted it in a non-economic, non-peer-reviewed publication. *Id.* at 151:22-152:13. Prof. Elhauge’s testimony is based on a mathematical model that purports to identify possible patent litigation settlement dates. *See* Hamburger Decl., Ex. 1 (Elhauge Rep.) ¶ 22 tbl. 1. Among the model’s numerical inputs are assumptions about the merits of the Namenda IR patent litigation and the costs of litigating that case through appeal, which were provided by Plaintiff expert George Johnston. *Id.* at ¶¶ 17-20. Prof. Elhauge also assumes that the patent litigation would have ended by [REDACTED], and incorporates into his model the parties’ potential profits from sales of Namenda IR and generic memantine using that date as the end of litigation. *Id.* at ¶ 19. In contrast, Mr. Johnston opines that the patent litigation would have ended [REDACTED], in [REDACTED], and Plaintiffs’ damages expert, Dr. Russell Lamb, utilizes [REDACTED] as the end of litigation in his damages models. Hamburger Decl., Ex. 2 (Am. Expert Report, Dr. Russell L. Lamb, dated Sept. 20, 2017) (“Lamb Rep.”) ¶¶ 129, 141.

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

But the amendment also resulted in significant financial benefits for Forest that Prof. Elhauge ignores in his calculation. [REDACTED]

[REDACTED]

[REDACTED] Second, by shifting manufacturing to Mylan, Forest expected to reduce its “best price” liability to Medicaid by [REDACTED]. Hamburger Decl., Ex. 4 (Expert Report of Philip Green, dated Oct. 9, 2017) ¶¶ 43-46, 75-79.

Prof. Elhauge’s model depends on calculating the parties’ “bargaining power” from the actual settlement, and then finding a generic entry date that would maintain this “bargaining power” if the parties settled for “no payment” from Forest to Mylan. Hamburger Decl., Ex. 1 (Elhauge Rep.) ¶¶ 62-65 (explaining that he calculates “bargaining power” as the percentage of the total settlement gains that accrue to each party). Based on the assumptions discussed above, the model identifies [REDACTED] as the “no-payment settlement” entry date, which Prof. Elhauge interprets to mean that “if the parties had settled without a reverse payment, they would have agreed to a settlement with an entry date of [REDACTED], about [REDACTED] prior to the settlement entry date of January 11, 2015 agreed upon with the reverse-payment settlement.”

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Hamburger Decl., Ex. 17 (Agovino (Forest) Dep.) at 75:6-76:6;
Hamburger Decl., Ex. 18 (Ryan (Forest 30(b)(6)) Dep.) at 394:16-395:4.

III. ARGUMENT

Plaintiffs bear the burden of proving that their proffered expert testimony is admissible. *Baker v. Urban Outfitters, Inc.*, 254 F. Supp. 2d 346, 353 (S.D.N.Y. 2003). Expert testimony must be “sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993) (citation omitted). Thus, a court must not “admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Furthermore, a court cannot admit testimony that does not comport “with the substantive law[s]” at issue. *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 572-73 (S.D.N.Y. 2007).

If the proposed testimony is relevant, this Court also must ensure that it is “reliable.” *Daubert*, 509 U.S. at 489. When assessing this issue, the Court should consider whether the expert’s methodology “had been and could be tested, whether it had been subjected to peer review, what its error rate was, and whether scientific standards existed to govern the theory or technique’s application.” *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005).

Finally, even relevant, reliable expert testimony must be excluded where it “usurps either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.” *Nimely*, 414 F.3d at 397 (citation omitted). Such

testimony does not assist the jury, but rather attempts to “tell the jury what results to reach” and thereby impermissibly “substitute the expert’s judgment for the jury’s.” *Id.* (citation omitted).

A. Prof. Elhauge’s Opinions Do Not Comport With *Actavis*

As this Court recognized, *Actavis* only prohibits certain reverse payments that are “large and unjustified.” *Actavis*, 133 S. Ct. at 2237; *Namenda I*, 2016 U.S. Dist. LEXIS 128349, at *41-42. The inquiry into whether a payment is large or unjustified should be informed by “virtues” stemming from the payment, including “traditional settlement considerations, such as avoided litigation costs or fair value for services.” *Actavis*, 133 S. Ct. at 2236. This is because the presence or absence of these virtues may show whether the payment was for legitimate purposes, or instead because “the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Id.* at 2235. Payments from a brand to a generic thus are not problematic unless they are made as “payment in return for staying out of the market.” *Id.* at 2235-36 (noting that “the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences” where the payment was for reasons other than to buy delay).

Prof. Elhauge’s model, however, is at odds with *Actavis*. It finds that *any* payment to a generic causes delay, regardless of whether it was large, and even where the payment was for a reason specifically authorized by *Actavis*, such as saved litigation costs. See Hamburger Decl., Ex. 14 (Elhauge Dep. Tr. I) at 23:18-21. For example, Mr. Johnston has opined that Forest’s future litigation costs if it had continued litigating the patent case would have been [REDACTED].

Hamburger Decl., Ex. 1 (Elhauge Rep.) ¶ 20. Yet Prof. Elhauge’s model calculates that a [REDACTED]

[REDACTED]

[REDACTED]. Hamburger

Decl., Ex. 5 (Expert Report of Lona Fowdur, Ph.D., dated Oct. 9, 2017) ¶ 65. Thus, Prof. Elhauge's model finds that small payments made for "avoided litigation costs" cause delay, even though *Actavis* is clear that such payments are lawful. 133 S. Ct. at 2236.

The same is true with respect to Prof. Elhauge's treatment of expected benefits to the brand company that result from the payment, which may negate the inference that the payment was an effort to share monopoly profits in order to obtain delayed generic entry. *Actavis*, 133 S. Ct. at 2235-36. Even if the brand receives benefits greater than the amount of its payment, and there is thus no reverse payment from the brand, Prof. Elhauge's model finds that the payment caused delay. For instance, if Forest received [REDACTED] in Medicaid savings due to the 2010 Lexapro AG amendment with Mylan — which is [REDACTED] more than the "reverse payment" calculated by Prof. Elhauge — then Prof. Elhauge's model still finds that the deal caused delay and that generic entry should have occurred on [REDACTED], just two days later than the entry date his model calculates if Forest had received no benefits from the deal. Hamburger Decl., Ex. 15 (Elhauge Dep. Tr. II) at 319:20-320:23. Thus, even where a deal makes economic sense because it would provide the brand with more in benefits than it paid to enter the deal — wholly apart from any benefits obtained by preserving part of the remaining patent term — Prof. Elhauge's model finds anticompetitive delay.

In short, Prof. Elhauge's model relies on a presumption that all reverse payments cause anticompetitive delay, even though "a reverse payment is not presumptively unlawful." *Namenda I*, 2016 U.S. Dist. LEXIS 128349, at *41-42 (citing *Actavis*, 133 S. Ct. at 2231, 2233, 2237); see also *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 U.S. Dist. LEXIS 127748, at *39 (S.D.N.Y. Sept. 22, 2015). *Actavis* requires only that settlements "not unlawfully restrict competition"; it "does not demand that the brand maximize competition." *Actos*, 2015

U.S. Dist. LEXIS 127748, at *50 (citing *King Drug Co. of Florence, Inc. v. SmithKline Beecham, Corp.*, 791 F.3d 388, 409 (3d Cir. 2015)), *rev'd on other grounds*, 848 F.3d 89 (2d Cir. 2016)). Because Prof. Elhauge's model and proposed testimony do not distinguish between lawful and unlawful reverse payments, Prof. Elhauge's opinions on alternative generic entry dates should be stricken. See *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000) (rejecting expert opinion that failed to "separate lawful from unlawful conduct").

B. Prof. Elhauge's Proposed Testimony Is Utter Speculation, Internally Inconsistent, And Contradicted By The Evidence

Prof. Elhauge argues that because a "no-payment" settlement with an entry date of [REDACTED] would be profitable to both Forest and Mylan, such a settlement was "clearly feasible." Hamburger Decl., Ex. 1 (Elhauge Rep.) ¶ 64. Based on nothing more than his model's indication that such a date would have been "feasible" (i.e., economically rational), Prof. Elhauge leaps to the conclusion that "if the parties had settled without a reverse payment, they *would have* agreed to a settlement with an entry date of [REDACTED]." *Id.* at ¶ 65 (emphasis added). But this conclusion is directly contradicted by the undisputed factual record.

Prof. Elhauge admits [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Hamburger Decl., Ex. 17 (Agovino (Forest) Dep.) at 75:6-76:6; Hamburger Decl., Ex. 18 (Ryan (Forest 30(b)(6)) Dep.) at 394:16-395:4 (testifying that Forest would not have settled for entry in 2012).

Thus, regardless of whether Prof. Elhaug's model indicates that such a settlement was feasible (i.e., economically rational), it does not show that the settlement actually would have happened.

Prof. Elhaug himself refused to opine that other settlements would have been reached merely because they were "feasible." For example, he disagreed that Mylan "would have settled for any date through the expiration of the patent without any payment from Forest," even though he believes that "it would have been feasible for them to have done so." Hamburger Decl., Ex. 14 (Elhaug Dep. Tr. I) at 52:15-21, 185:11-20 (agreeing that settlement at any entry date "would be feasible" for Mylan, but arguing that Mylan "would actually exercise what bargaining power they had to negotiate something better"). Moreover, he has conceded that one must consider whether the parties viewed a purportedly "rational" option as one that actually could be achieved, because "something might appear rational to third parties or it might be in the abstract rational, but you always have to compare it to what [the parties'] own perception of but-for alternatives were." Hamburger Decl., Ex. 15 (Elhaug Dep. Tr. II) at 259:13-260:2.

Plaintiffs' alternative [REDACTED] negotiated entry date is thus similar to the theory rejected in *In re Wellbutrin XL Antitrust Litigation*, where one party "expressly and unwaveringly refused to settle" on terms that the plaintiffs argued would have been adopted in an alternate settlement. 133 F. Supp. 3d 734, 757-58 (E.D. Pa. 2015). When the Third Circuit affirmed, it noted that plaintiffs must produce sufficient evidence for a reasonable jury "to conclude that it is more likely than not that [the parties] would have entered into a license agreement in the counterfactual world," and even if the parties had an incentive to do so that *does not raise a genuine issue of fact* about whether "they would have reached an agreement." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 167 & n.57 (3d Cir. 2017).

The opinion that Mylan would have accepted a “no-payment” settlement with entry on [REDACTED], also conflicts with other opinions offered by Prof. Elhauge. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]. But if that were true, then why would Mylan ever agree to a “no-payment” settlement with entry on [REDACTED], since that would result in the same saved litigation costs and [REDACTED] in expected profits that Prof. Elhauge opines were insufficient incentives for Mylan to walk away from the patent litigation?

Similarly, the “bargaining power” measurement that Prof. Elhauge relies on to calculate “feasible” entry dates leads to irrational outcomes. For instance, Prof. Elhauge argues that even though it was feasible for Mylan to have accepted a later entry date, Prof. Elhauge would expect Mylan to use its bargaining power to negotiate an earlier entry date [REDACTED]. *Id.* at 52:15-21. But according to Prof. Elhauge’s model, the more bargaining power that Mylan has, the *later* generic entry should occur; if Mylan had 100% bargaining power, the model finds a “no-payment” entry date [REDACTED]. *Id.* at 50:25-51:10.

Not only that, but certain assumptions in Prof. Elhauge’s model conflict with the opinions of Plaintiffs’ other purported experts. For example, Prof. Elhauge assumes that [REDACTED] was the expected end of the patent litigation, which is [REDACTED] end of litigation date predicted by Mr. Johnston — Plaintiffs’ purported patent litigation expert — and that Dr. Lamb used to calculate Plaintiffs’ claimed damages. Hamburger Decl., Ex. 2 (Lamb Rep.) ¶¶ 129, 141. By selecting an earlier date that no other Plaintiff expert endorses,

Prof. Elhaug increases the delay that his model calculates by approximately five months. See Hamburger Decl., Ex. 1 (Elhaug Rep.) ¶ 79, fig. 14.

Finally, Plaintiffs have not demonstrated that a model based on “bargaining strength” is a reliable indicator of possible settlement entry dates. Defendants have found no articles in peer-reviewed journals that advocate using bargaining strength models to predict the outcome of settlement negotiations, and Prof. Elhaug apparently is unaware of studies validating the use of bargaining strength for such purposes. *United Food & Commer. Workers Local 1776 v. Teikoku Pharma USA*, No. 14-md-02521, 2017 U.S. Dist. LEXIS 182940, at *123-24 (N.D. Cal. Nov. 3, 2017) (“*Lidoderm*”) (discussing Prof. Elhaug’s testimony).

Only one court has accepted Prof. Elhaug’s untested, non-peer-reviewed model using “bargaining strength” to predict economically feasible settlement outcomes, but that case, *Lidoderm*, is inapposite. There, the defendants identified no assumptions relied upon by Prof. Elhaug that were contrary to the evidence, and no illogical outcomes resulting from his model. *Id.* at *69, 126. Here, by contrast, Prof. Elhaug’s predicted “no-payment” settlement entry date (1) is contradicted by undisputed evidence that such a settlement was not possible, (2) conflicts with Prof. Elhaug’s opinion that Mylan would not have accepted only its saved litigation costs and expected profits upon generic entry to end the case, and (3) relies on assumptions about the effect of bargaining power on settlement entry dates that are the opposite of what economic sense would predict.

Moreover, Prof. Elhaug concedes that the actual settlement here indicates that Forest had up to a 94.9% chance of prevailing in the patent litigation, which is consistent with the actual entry date that Forest agreed to with Mylan: permitting generic entry after 93% of the remaining patent term had expired. Hamburger Decl., Ex. 1 (Elhaug Rep.) ¶¶ 6, 68. This stands in stark

contrast to *Lidoderm*, where Prof. Elhauge opined that the defendant could not have rationally agreed to the settlement if its likelihood of success in the patent litigation was any higher than 15.1%. 2017 U.S. Dist. LEXIS 182940, at *123.

C. Prof. Elhauge's Opinions About When Entry "Would Have" Occurred Improperly Attempt To Usurp The Role Of The Jury


If the Court finds that Prof. Elhauge's proposed testimony is admissible, at a minimum it should prohibit him from opining that the parties "would have agreed to a settlement with an entry date [REDACTED]." Hamburger Decl., Ex. 1 (Elhauge Rep.) ¶ 65. For Plaintiffs' claims to succeed, the jury will need to decide that Forest and Mylan would have settled the patent litigation and allowed Mylan to enter earlier than the date specified in the actual settlement agreement. Because the jury is "fully capable of reaching such a conclusion by itself, [and] might give undue deference to the expert's conclusion," this Court must "guard against admission of opinions that would simply tell the jury what result to reach." *Aventis Envtl. Sci. USA LP v. Scott's Co.*, 383 F. Supp. 2d 488, 516-17 (S.D.N.Y. 2005) (prohibiting expert testimony); *see also Nimely*, 414 F.3d at 397 (finding that expert testimony that tells the jury "what result to reach" does not assist the jury, but instead "attempts to substitute the expert's judgment for the jury's") (internal quotation marks and citation omitted). That is why even though the *Lidoderm* court declined to prohibit Prof. Elhauge's testimony altogether, it limited him to opining only that in "his view the parties would have been rationally motivated to agree to settlement allowing [] early entry," and held that he "cannot testify that the parties *would have* agreed to entry on a date certain, as that impinges on a determination left up to the jury." *Lidoderm*, 2017 U.S. Dist. LEXIS 182940, at *126 (emphasis in original). Prof. Elhauge's testimony should be limited similarly if the Court otherwise permits it.

IV. CONCLUSION

For the foregoing reasons, this Court should exclude certain opinions and proposed testimony of Prof. Elhauge, or alternatively, limit it as described in Section III.

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